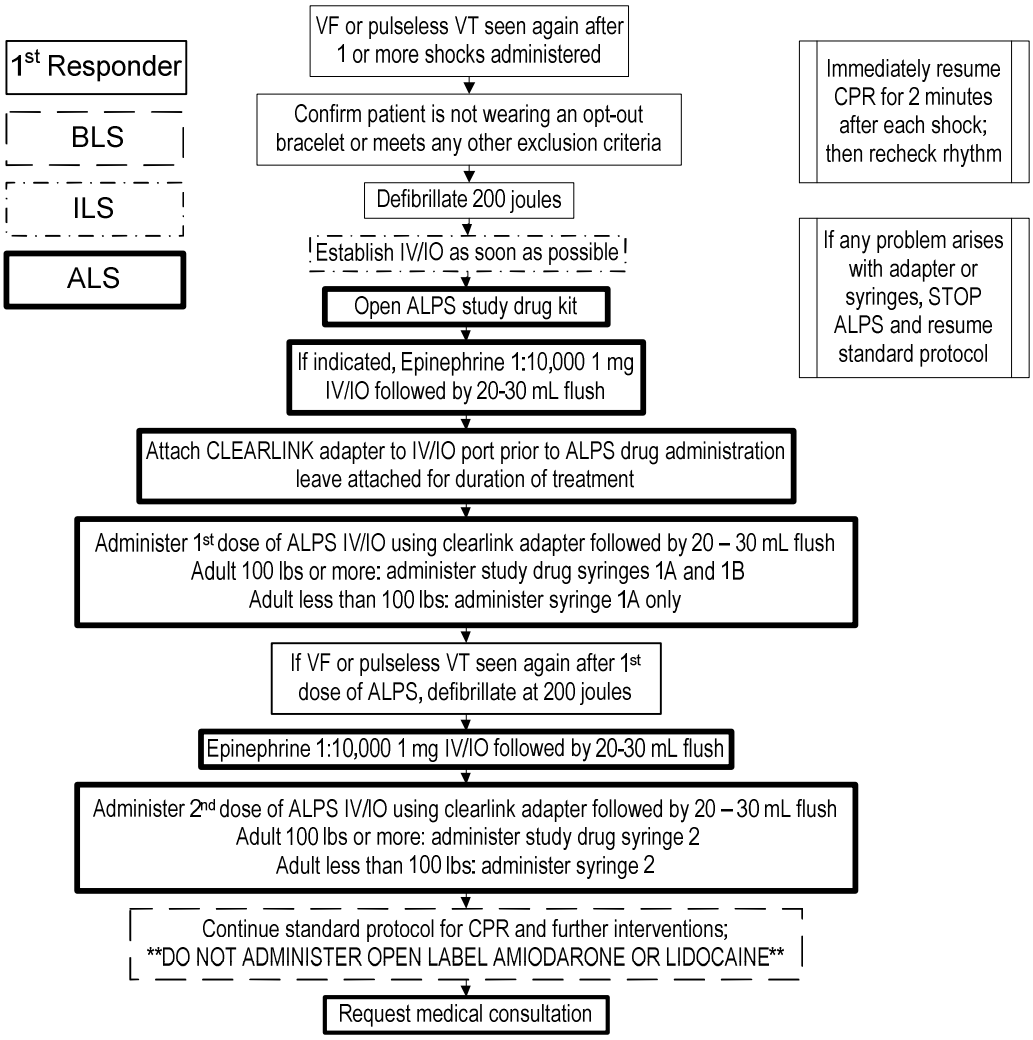
Initiated: 2/23/13	**MILWAUKEE COUNTY EMS RESEARCH PROTOCOL**	Approved by: M. Riccardo Colella, DO, MPH, FACEP
Completed:	**AMIODARONE LIDOCAINE PLACEBO STUDY**	WI EMS Approval Date: 1/17/13
Revised: 8/1/13		Page 1 of 1

Primary Objective	Eligibility	Exclusion Criteria
1) Determine if survival to hospital discharge is improved with early therapeutic administration of Captisol- Enabled (PM101) formulation of IV amiodarone 2) Determine if survival to hospital discharge is improved with early therapeutic administration of: a) Lidocaine compared with placebo b) PM101 compared with lidocaine	1) 18 years or older 2) Non-traumatic cardiac arrest Initial rhythm VF or pulseless VT 3) Conversion from another pulseless rhythm to VF or pulseless VT 4) Incessant or recurrent VF/VT after receipt of 1 or more shocks 5) Established vascular access	1) Initial rhythm asystole or PEA without transition to pulseless VT or VF 2) Valid DNR or POLST order 3) Blunt, penetrating, or burn-related injury 4) Exsanguination 5) Patient is a minor 6) Patient is pregnant 7) Patient is a prisoner 8) Prior treatment with lidocaine or amiodarone during resuscitation 9) Known allergy to lidocaine or amiodarone 10) Patient wearing opt-out bracelet



NOTES:

- Study drug MUST be administered using the clearlink adapter
- Any time a non-shockable rhythm is identified, assess pulse after 2 min CPR and treat accordingly. Should VF/VT recur, resume treatment with study drug where last left off, using remaining syringes.
- After administering study treatment, no open label amiodarone or lidocaine should be administered.
- If syringe(s) in kit are broken or malfunction, STOP ALPS and follow standard protocol using open label amiodarone or lidocaine.
- Turn over ALPS written script to receiving hospital ED staff (1 to treating physician, 1 to nurse, 1 to tech/nurse)
- Retain study drug kit with any spent/unspent syringes. After reporting tracking number and usage to research staff, discard syringes according to standard protocol for discarding medications.
- Thoroughly document study procedures in PCR, including kit tracking number and study number.